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MAR 11 2009

James V. Lilly
Kagan Binder, PLLC
221 Main St. North, Suite 200
Stillwater, MN 55082

Re: Patent Term Extension
Applications for
U.S. Patent Nos. 5,258,028
5,336,263
5,571,182

Dear Mr. Lilly:

The USPTO is in receipt of your letter of March 5, 2009, relating to the status of the patent term extension applications filed in each of the above referenced patent numbers.

It is noted that 35 U.S.C. § 156 expressly states (in relevant part):

> ∴. . the Secretary reviewing the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination and **shall publish in the Federal Register a notice of such determination**.

35 U.S.C. § 156(d)(2)(A)(ii) (emphasis added).

Please note that the statutory requirement of publication of FDA's determination of the regulatory review period in the Federal Register occurred on February 11, 2009 at 74 Fed. Reg. 6901. The Federal Register notice sets forth two time periods for public comment. Specifically, the 180-day period of 35 U.S.C. § 156(d)(2)(B)(i) (relating to submission of due diligence petitions) and the 60-day period provided for in 21 C.F.R. § 60.24 (relating to requests for revision of the regulatory review period determination).

Action on the referenced patent term extension applications by the USPTO cannot occur until FDA has made their final determination with respect to the regulatory review period as published in the Federal Register of February 11, 2009, after which FDA will communicate their findings to the USPTO. Please note that the first time period concludes on April 13, 2009, and the second time period concludes on August 10, 2009. Thus, Applicant's letter of March 5, 2009, stating, "we have received no word from the United States Patent and Trademark Office concerning these petitions" is premature. Applicant may wish to review MPEP sections 2756 and 2757 relating to correspondence between the USPTO and the regulating agency and the duties of the regulatory agency under 35 U.S.C. § 156.

Any further correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-0100

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755. E-mail inquiries should be directed to mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: Macroplastique® Implants
FDA Docket Nos.: FDA-2008-E-0091
FDA-2008-E-0099
FDA-2008-E-0204